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## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Chappel, R. et al.

Examiner: H

Hines, J.

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For:

Leptospira pathogens

**EXHIBIT I** 



ADDRESS:

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Victoria 3099

PHONE (BH): PHONE (AH): (03) 9418 1115

MARITAL STATUS:

0414 748 308 Married

NATIONALITY:

Australian

DATE OF BIRTH:

25 February 1946

PLACE OF BIRTH:

Ivanhoe, Victoria, Australia

# **Professional Employment**

NATIONAL SEROLOGY REFERENCE LABORATORY, (AUSTRALIA)
Quality Manager

1999-Current

Description:

Manage the establishment, implementation and maintenance of the quality management system (QMS) in accordance with the International Standard (ISO 9004), NATA General Requirements for Registration (ISO/IEC 17025) and TGA Code of Good Manufacturing Practice (cGMP). Responsible for maintaining the quality manual. Quality Manager, as document controller, ensures the Quality Manual, documented procedures, work instructions and other critical QMS documents are appropriately controlled and implemented. The Quality Manager ensures by regular internal audits that all facilities, test equipment, quality system documents and manuals meet the required standards. The Quality Manager reports the results to the Director for review as a basis for improving the system.

Maintains organisation standards including, but not limited to, quality monitoring, quality evaluation and validation procedures. Continually reviews the QMS and is responsible for developing and implementing improvements in collaboration with the Director, to further develop the quality system philosophy within the NRL. Provides training on new quality system procedures to staff and others as necessary

VICTORIAN INSTITUTE OF ANIMAL SCIENCE, DEPT. OF NATURAL RESOURCES AND ENVIRONMENT, VICTORIA

Quality Manager 1995-1998 & Research Scientist 1972-1998

**Description & Responsibilities:** 

Leader of numerous funded research projects since 1974, and participant in other research projects. Quality Manager for VIAS since 1995. As such, led the VIAS diagnostic service to ISO 9000 and Certified Laboratory Practice certification in 1997. Established and led collaborative research teams involving other government institutes, university departments, field veterinarians, and interstate and overseas scientific institutions. Established the team that brought quality certification to a complex diagnostic service. Author of many

## Curriculum Vitae

## Roderick Chappel

scientific papers and reports, and of quality system documentation. Have made many oral presentations. Areas of expertise include quality assurance, microbiology, Leptospirosis in livestock and the development and evaluation of diagnostic tests in immunology and biochemistry

## Education

UNIVERSITY EDUCATION

UNIVERSITY OF MELBOURNE, MELBOURNE 1972 Doctor of Philosophy

UNIVERSITY OF MELBOURNE, MELBOURNE 1967 Bachelor of Agricultural Science

Member of the Australian Society for Microbiology

NATA External Auditor Training

**NATA Technical Assessor** 

## **Achievements**

### Quality management (1999-2001)

- Quality Manager for NRL
- Maintained ISO 9001 certification, ISO 17025 accreditation and GMP
- Adopted Fast Track software to convert paper based system to electronic system
- · Developed improved management review integrated with business management
- Provided internal training and external training and consultancy in quality management
- NATA technical assessor

#### Quality management (1995-1998)

- Quality Manager for Institute
- Established Quality Committee for coordinating quality management areas
- · Established diagnostic team to work towards certification
- · Adopted Paradigm Quality software
- · Achieved ISO 9002 certification for diagnostic service
- · Achieved Certified Laboratory Practice for diagnostic service
- Overview of Good Laboratory Practice (GLP)
- Supported interlaboratory proficiency testing program

## Leptospirosis (1980-1998)

#### Established collaborations

- Monash University
- Regional Veterinary Laboratory, Bendigo
- · Other Victorian regional laboratories
- Major pig producer

## Roderick Chappel

## Curriculum Vitae

- Vaccine companies
- South Australian Department of Agriculture
- Pasteur Institute, New Caledonia and Paris

#### Developed new technology

- Immunoassays for leptospiral antigen
- DNA hybridisation
- Immunofluorescence
- Immunogold silver staining
- · Improved selective culture medium
- Polymerase chain reaction (PCR) methods

#### International aid

- Australian Centre for International Agricultural Research (ACIAR)
- Transfer of ELISA technology
- Visits to Indonesia for technology transfer
- Trained Indonesian scientist in Victoria

#### New knowledge

- Discovered Leptospira fainei serovar hurstbridge
- Discovered by PCR existence of other leptospiral serovars

#### Human leptospirosis

- Serovar hurstbridge as a human pathogen.
- PCR for human leptospirosis diagnosis

#### Other research outcomes

- · Improved standard microscopic agglutination test
- Experimental infection studies
- Vaccine trials
- · Major serological studies in commercial pigs
- · Serological studies in dairy cattle
- Studied role of maternally-derived antibody
- Compared eradication strategies
- · Produced video for farmers undertaking eradication
- PCR available diagnostically

#### Commercialisation

- · Patented use of newly discovered organism
- Commercial licensing of newly discovered organism

## Delayed release technology (1992-1995)

- Managed animal testing program
- Prepared reports for commercial milestones

## Fowl cholera (1990-1992)

Collaborated with Monash University regarding molecular vaccine

#### Diagnostic bacteriology (1990-1992)

Rostered scientist

# Curriculum Vitae



## **Annual reports** (1990-1993)

Contributed to editing

## Acting Section Leader, Biochemistry (1985-1988)

- Supervised clinical biochemistry
- Supervised research functions

#### Association with Monash University (1983-1986)

- · Honorary research associate
- · Honorary senior lecturer

## Safety management (1974-1985)

- Radiation Safety Officer
- Safety Committee

## Bovine brucellosis (1974-1980)

- · Contributed to national eradication program
- Evaluated available serological tests
- · Determined test sensitivities to different antibody isotypes
- · Developed radioimmunoassay as supplementary test
- · Studied prozoning in complement fixation test
- Invited speaker at brucellosis eradication conference, Kuala Lumpur

## Animal experimentation (1972-1988)

· Pigs, dogs, mice, rabbits, guinea pigs

### Dog vaccination against hydatid tapeworm (1972-1974)

Biochemical aspects

## Ph.D. studies, University of Melbourne (1967-1972)

- Isolated of pig growth hormone (PGH)
- Developed PGH radioimmunoassay
- · Studied relationships between PGH and growth, carcass composition

**Publications** 



#### Refereed Publications

Gust, A., Walker, S., **Chappel, R.J.**, and Dax, E.M. (2001) Anti-HIV quality assurance programs in Australia and the southeast Asian and Western Pacific regions. Accred. Qual. Assur. **6**, 168-172.

Perolat, P., Chappel, R.J., Adler, B., Baranton, G., Bulach, D.M., Billinghurst, M.L., Letocart, M., Merien, F. and Serrano, M.S. (1998) Description, characterization and phylogenetic analysis of *Leptospira fainei* sp. nov., isolated from pigs in Australia. *Int J Syst Bact* 48, 851-858.

Chappel, R.J., Driesen, S.J., Khalik, D.A., Moore, K.M., Adler, B., Billinghurst, M.L. and Perolat, P. (1997) Leptospiral infection of pig kidneys with visible lesions, studied using a polymerase chain reaction technique. *Manipulating Pig Production* VI 303.

Chappel, R.J., Khalik, D.A., Adler, B., Bulach, D.M., Faine, S., Perolat, P. and Vallance, V. (1998) Serological titres to *Leptospira fainei* serovar hurstbridge in human sera in Australia. *Epidemiology and Infection* 121, 473-475.

Chappel, R.J., Prime, R.W., Millar, B.D., Jones, R.T., Cutler, R.S. and Adler, B. (1998) Prevalence and geographic origin of pigs with serological evidence of infection with *Leptospira interrogans* serovar *pomona* slaughtered in abattoirs in Victoria, Australia. *Vet. Microbiol.* **62**, 235-242.

Moore, K.M., Connaughton, I.D., Callinan, A.P.L., Khalik, D.A. and **Chappel, R.J.** (1997) Relationships between reproductive performance and serological titres to leptospiral serovars hurstbridge and bratislava in a Victorian pig herd. *Manipulating Pig Production* **VI** 79.

**Chappel, R.J.**, Billinghurst, M.L., Adier, B., Bulach, D.M., Khalik, D., Merien, F., Serrano, M.S., Wilson, R.J. and Perolat, P. (1996) Isolation from pigs of a pathogenic leptospire of a new genospecies and serogroup (serovar *hurstbridge*), and a serological study of its distribution and possible veterinary significance. *Proceedings of the First Meeting of the International Leptospirosis Society*.

Perolat, P., Chappel, R.J., Letocart, M., Merien, F. and Baranton, G. (1996) Molecular and phenotypic characterization of "hurstbridge" strains as a new genomic species of pathogenic Leptospira, Proceedings of the First Meeting of the International Leptospirosis Society.

Chappel, R.J. and Adler, B. (1995) Leptospirosis - more than meets the eye. *Manipulating Pig Production V* 231.

Bills, M.M., Medd, J.M., Chappel, R.J. and Adler, B. (1993) Construction of a shuttle vector for use between *Pasteurella multocida* and *Escherichia coli. Plasmid* 30, 268-273.

**Chappel, R.J.** (1993) Leptospirosis. Pathology, Bacteriology and Serology. Australian Standard Diagnostic Techniques for Animal Diseases. Standing Committee on Agriculture and Resource Management.

Chappel, R.J., Billinghurst, M.L., Wan, S.S., Hennessy, D.P., Ellis, W.A. and Adler, B. (1993) Leptospires of serovar bratislava as a possible pathogen in Australian pigs. *Manipulating Pig Production IV* 253.

Zhu, S., Chappet, R. and Amon, L. (1993) [Restriction endonuclease analysis of Pomona serogroup of Leptospira interrogans]. Wei. Sheng. Wu. Hsueh. Pao. 33, 374-377.

Chappel, R.J., Prime, R.W., Millar, B.D., Mead, L.J., Jones, R.T. and Adler, B. (1992) Comparison of diagnostic procedures for porcine leptospirosis. *Vet. Microbiol.* **30**, 151-163.

Chappel, R.J., Ellis, W.A., Adler, B., Amon, L., Millar, B.D., Zhu, S.S. and Prime, R.W. (1992) Serological evidence for the presence of *Leptospira interrogans* serovar *bratislava* in the Australian pig herd. *Aust. Vet. J.* **69**, 119-120.

Chappel, R.J. and Cutler, R.S. (1992) How an understanding of leptospirosis in Australian livestock can help you to combat human infection. In: *Zoonoses. Australian Veterinarians in Public Health*. pp. 275-281. Proceedings of the Postgraduate Committee in Veterinary Science, University of Sydney.

Chappel, R.J., Prime, R.W., Cutler, R.S., Jones, R.T., Millar, B.D. and Adler, B. (1990) Antileptospiral antibodies in Australian pig farmers. *Med. J. Aust.* **152**, 105.

**Chappel, R.J.**, Adler, B., Jones, R.T. and Millar, B.D. (1990) Leptospirosis. In: Gardner, J.A.A., Dunkin, A.C. and Lloyd, L.C. (Eds.) *Pig Production in Australia*, 2nd edn. pp. 211-214. Sydney: Butterworths.

**Chappel, R.J.**, Adler, B., Cutler, R.S., Jones, R.T. and Millar, B.D. (1989) The role and effectiveness of antileptospiral vaccines in pigs. *In "Manipulating Pig Production II", eds J.L.Barnett and D.P.Hennessy* 256-59, 265-272.

**Chappel, R.J.**, Millar, B.D., Adler, B., Hill, J., Jeffers, M.J., Jones, R.T., McCaughan, C.J., Mead, L.J. and Skilbeck, N.W. (1989) *Leptospira interrogans* serovar *hardjo* is not a major cause of bovine abortion in Victoria. *Aust. Vet. J.* **66**, 330-333.

Chappel, R.J. (1989) Diagnosis of bovine brucellosis: principles, practice and problems. Surveillance 16, 3-6.

McCormick, B.M., Millar, B.D., Monckton, R.P., Jones, R.T., **Chappel, R.J.** and Adler, B. (1989) Detection of leptospires in pig kidney using DNA hybridisation. *Res. Vet. Sci.* 47, 134-135.

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**Chappel, R.J.**, Adler, B., Jones, R.T., Mead, L., Millar, B.D., Prime, R.W. and Skilbeck, N.W. (1987) Studies on the incidence and industry significance of porcine leptospirosis. *Manipulating Pig Production* I, 232.

Chappel, R.J., Adler, B., Millar, B.D. and Jones, R.T. (1987) Porcine leptospirosis. *Proceedings of the Postgraduate Committee in Veterinary Science, University of Sydney* **95, "Pig Production"**, 1112-1118.

Jones, R.T., Millar, B.D., Chappel, R.J. and Adler, B. (1987) Macroscopic kidney lesions in slaughtered pigs are an inadequate indicator of current leptospiral infection. *Aust. Vet. J.* **64**, 258-259.

Millar, B.D., Chappel, R.J. and Adler, B. (1987) Detection of leptospires in biological fluids using DNA hybridisation. *Vet. Microbiol.* 15, 71-78.

Millar, B.D., Chappel, R.J., Adler, B., Driesen, S.J. and Jones, R.T. (1987) Effect of maternal vaccination on the susceptibility of growing pigs to leptospiral infection. *Vet. Microbiol.* 15, 79-87.

Skilbeck, N.W. and Chappel, R.J. (1987) Immunogold silver staining for visualization of leptospires in histologic sections. *J. Clin. Microbiol.* **25**, 85-86.

Adler, B., Faine, S., Christopher, W.L. and Chappel, R.J. (1986) Development of an improved selective medium for isolation of leptospires from clinical material. *Vet. Microbiol.* 12, 377-381.

Chappel, R.J., Adler, B., Ballard, S.A., Faine, S., Jones, R.T., Millar, B.D. and Swainger, J.A. (1985) Enzymatic radioimmunoassay for detecting *Leptospira interrogans* serovar *pomona* in the urine of experimentally-infected pigs. *Vet. Microbiol.* 10, 279-286.

Ballard, S.A., Adler, B., Millar, B.D., **Chappel, R.J.**, Jones, R.T. and Faine, S. (1984) The immunoglobulin response of swine following experimental infection with *Leptospira interrogans* serovar pomona. Zentralblatt fur Bakteriologie, Mikrobiologie und Hygiene, Abt. Orig. A **256**, 510-517.

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Hayes, J. and **Chappel, R.J.** (1982) A comparison of the results of the brucellosis radioimmunoassay and other serological tests in experimentally infected cattle. *J. Hyg.*, *Camb.* **88**, 21-28.

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**Chappel, R.J.**, McNaught, D.J., Bourke, J.A. and Allan, G.S. (1978) The diagnostic efficiency of some serological tests for bovine brucellosis. *J. Hyg.*, *Camb.* 80, 373-384.

Chappel, R.J., McNaught, D.J., Bourke, J.A. and Allan, G.S. (1978) Comparison of the results of some serological tests for bovine brucellosis. *J. Hyg.*, Camb. **80**, 365-371.

McNaught, D.J., Chappel, R.J., Allan, G.S., Bourke, J.A. and Rogerson, B.A. (1977) The effects of  $\lg G_2$  and of antigen concentration on prozoning in the complement fixation test for bovine brucellosis. *Res. Vet. Sci.* 22, 194-197.

Allan, G.S., Chappel, R.J., Williamson, P. and McNaught, D.J. (1976) A quantitative comparison of the sensitivity of serological tests for bovine brucellosis to different antibody classes. *J. Hyg.*, *Camb.* 76, 287-298.

Chappel, R.J., Williamson, P., McNaught, D.J., Dalling, M.J. and Allan, G.S. (1976) Radioimmunoassay for antibodies against *Brucella abortus*: a new serological test for bovine brucellosis. *J. Hyg.*, Camb. 77, 369-376.

Chappel, R.J. and Dunkin, A.C. (1975) Relation of concentration of growth hormone in blood plasma to growth rate and carcass characteristics in the pig. *Animal Production* **20**, 51-61.

Herd, R.P., Chappel, R.J. and Biddell, D. (1975) Immunization of dogs against *Echinococcus* granulosus using worm secretory antigens. *International Journal of Parasitology* 5, 395-399.

Chappel, R.J. and Camegie, P.R. (1974) Isolation of pig growth hormone under mild conditions. *International Journal of Biochemistry* 5, 187-191.

Chappel, R.J. (1973) Electrophoresis of pig growth hormone under acidic conditions. *International Journal of Biochemistry* 4, 421-424.

## **Conference Proceedings**

**Chappel, R.J.**, Driesen, S.D., Moore, K.A. and Khalik, D.A. (2001). New Leptospires Infecting Australian Pigs. *Australian Association of Pig Veterinarians Melbourne Proceedings* 2001, 5-8.

Chappel, R.J. (2000) Experiences in implementing a laboratory quality management system. Proceedings of the Victorian State Conference of the Australian Institute of Medical Scientists, Bendigo.

**Chappel, R.J.** (1999) Making quality management a help and not a hindrance. *Proceedings of the 17<sup>th</sup> NRL Workshop on Serology, Perth* 14.

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**Chappel, R.J.**; Marshall, R.B.; Collins-Emerson, J.; Khalik, D.A. and Stevenson, B. (1999) A serological study of leptospiral serovars bratislava and hurstbridge in New Zealand pigs. *Proceedings of the Second Meeting of the International Leptospirosis Society* xx

Sammons, N.G. and Chappel, R.J. (1999) Vaccination against Leptospira interrogans serovar bratislava improved reproductive performance in a commercial pig herd in Australia. Proceedings of the Second Meeting of the International Leptospirosis Society 17.

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**Chappel, R.J.**, Davies, P.R., Prime, R.W., Ellis, G., Adler, B., Cutler, R.S., Jones, R.T. and Millar, B.D. (1990) Can piglets be successfully vaccinated against leptospirosis in the presence of maternally-derived serum antibody? *Aust. Microbiologist* 11, 251.

Chappel, R.J., Adler, B., Jones, R.T., Mead, L.J., Millar, B.D. and Prime, R.W. (1989) The prevalence of antileptospiral antibodies in the sera of pigs slaughtered at Victorian abattoirs. *Aust. Microbiologist* 10, 347.

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## **Extension and Other Publications**

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Dax, E.M., Gust, A. and **Chappel, R.J.** (1999) HIV and HCV transmission through transfusion — what change in safety for what price? *Noah's Arc* 10: 53-56.

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## **Publications**

## Roderick James Chappel

Prime, R.W. and Chappel, R.J. (1990) Leptospirosis: a health threat to people and pigs. *Milne's Pork Journal* 12 (5), 36-37.

Chappel, R.J. (1989) Human leptospirosis is a debilitating disease. *Milne's Pork Journal* 11 (6), 14-15

Prime, R.W. and Chappel, R.J. (1989) Leptospirosis - a problem for people and pigs. *Pork Producer* 9 (10), 16,13

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**Chappel, R.J.** (1972) Pig growth hormone: isolation and radioimmunoassay in blood plasma. *Ph. D. Thesis, University of Melbourne*.

#### Video

**Chappel, R.J.** and others (1993) Control and Eradication of Leptospirosis in Australian Piggeries. Sedgwick, Victoria: Sedgwick Video Productions.

## Patent

Chappel, R.J. (1998) Novel Bacterial Pathogens. International patent application.

Prisone Approlateur (PP 3740026) element declaration doc-26 September, 2001

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DAVIE79.001A

For:

Leptospira pathogens

**EXHIBIT II** 

```
LOCUS
            LFU60594
                         1481 bp
                                     DNA
                                                     BCT
                                                               10-SEP-1998
DEFINITION
            Leptospira fainei 16S ribosomal RNA gene, partial sequence.
ACCESSION
            U60594
VERSION
            U60594.1 GI:1408219
KEYWORDS
SOURCE
            Leptospira fainei.
  ORGANISM Leptospira fainei
            Bacteria; Spirochaetales; Leptospiraceae; Leptospira.
REFERENCE
            1 (bases 1 to 1481)
  AUTHORS
            Perolat, P., Chappel, R.J., Adler, B., Baranton, G., Bulach, D.M.,
            Billinghurst, M.L., Letocart, M., Merien, F. and Serrano, M.S.
  TITLE
            Leptospira fainei sp. nov., isolated from pigs in Australia
  JOURNAL
            Int. J. Syst. Bacteriol. 48 Pt 3, 851-858 (1998)
  MEDLINE
            98404550
REFERENCE
            2 (bases 1 to 1481)
  AUTHORS
            Adler, B., Chappel, R.J., Baranton, G., Bulach, D.M.,
            Billinghurst, M.L., Letocart, M., Merien, F., Serrano, M.S. and
            Perolat, P.
  TITLE
            Direct Submission
            Submitted (12-JUN-1996) Microbiology, Monash University, Wellington
  JOURNAL
            Rd., Clayton, VIC 3168, Australia
FEATURES
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                                           314 t
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      121 actttccgaa aggaaagcta ataccggata gtcctgttgg atcacaagat ttgataggta
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11
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